Standard Operating Procedure – Revoking Patient Consent

This cover sheet controls the layout and components of the entire document.

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Department Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	February 28, 2006	SOP WG Review	All pages	Document Creation
1.0	February 28, 2006	SOP WG Approval	All pages	Document Creation
1.0	March 14, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process of patients withdrawing their consent from a clinical research trial and how their protected health information (PHI) authorization is affected.

2. Scope

This SOP advises all caBIG™ participants having access to applications supported by the NCICB on the HIPAA Privacy Rule's requirements concerning the withdrawal of patient consent and the use of the patient's PHI. The patient's rights and the rights of the research entity concerning use of the patient's PHI are listed in detail below.

3. Requirements

3.1 The HIPAA Privacy Rule gives individuals the right to revoke an authorization they have given at any time. The authorization must clearly state the individual's right to revoke and the process for revocation must either be set forth clearly on the authorization itself or the authorization can refer to the Notice of Privacy Practices. This revocation must be in writing and is not effective until the covered entity receives it.

3.2 The Privacy Rule permits, but does not require, a covered entity voluntarily to obtain patient consent for uses and disclosures of PHI for treatment, payment, and health care operations. By contrast, an authorization is required by the Privacy Rule for giving covered entities permission to use PHI for specified purposes, which are generally other than treatment, payment, or health care operations.

3.3 An authorization must specify a number of elements, including a description of the PHI to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the covered entity may make the disclosure, an expiration date or an expiration even that relates to the individual or the purpose of use or disclosure, and, in some cases, the purpose for which the PHI may be used or disclosed.

3.4 Covered entities may continue to use and disclose PHI that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study.

3.5 An individual may not revoke an authorization to the extent the covered entity has acted in reliance on the authorization. This reliance exception at 45 CFR 164.508(b)(5)(i) permits the continued use and disclosure of PHI already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. For example, the reliance exception would permit the continued use and disclosure of protected health information to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events. However, this reliance exception would not permit a covered entity to continue disclosing additional PHI to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.

3.6 While researchers may legally continue to use patient data upon which they have demonstrated reliance, even after the patient has revoked consent, it may be desirable for the institution to discard the patient data to avoid potential legal proceedings.

3.7 Additional state or local regulations may apply. If applicable, it is the responsibility of the local site to compliance with said regulations.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
4.2	N/A	Title 45 CRF Part 164, Uses and disclosures for which an authorization is required
4.3	AD-004	SOP for HIPAA Security Compliance
4.4	AD-005	SOP for Protecting Patient Privacy

5. Roles & Responsibilities

Role	Responsibility
NCICB Applications Director	• Develop a policy requiring cancer centers to have a written authorization from human subjects before using or disclosing their data using the caBIG™ environment. • Develop the Authorization that clearly states the individual's right to revoke their consent, as well as the process for doing so.
Principal Investigator	• Obtain Institutional Review Board (IRB) approval for all research involving Information in Identifiable Form (IIF). • Obtain authorization from human subjects that supply their data to the caBIG™ environment before disclosing it in any manner not previously described in the consent form.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all C3D adopters and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Revoking Patient Consent	This document provides the process for revoking patient consent.
2) Process Flow for Revoking Patient Consent	This document identifies the workflow activities, by role, for the steps identified for revoking patient consent.